

DEC 27 2004

K032434

**510(k) Summary**

(As required by 21 CFR 807.92)

Premarket Notification Number: Applied for

1. Submitter's Identification:

Cotronic Manufacturing  
4F, Block 4, Fu Yuan Ind. Zone,  
Jiu Wei, Xi Xiang, Bao An zone,  
Shen Zhen, China  
Tel: +86-755-2747-7681  
Fax: +86-755-2747-7680  
Contact: Mr. Shine Wan

Date Summary Prepared: July 15, 2003

2. Name of the Device:

Clinical Electronic Thermometer

3. Predicate Device Information:

Digital Thermometer classic type and flexible type, K023711, Acute Ideas Co.,  
Ltd.

4. Device Description:

The Clinical Electronic Thermometer is a thermometer intended for the  
determination of oral, axillary, and rectal body temperature determination in  
humans.

5. Intended Use:

The device measures the human body temperature from oral, axillary and rectal.  
The device is reusable and intended for clinical or home use on people of all  
ages.

6. Comparison to Predicate Devices:

The Clinical Electronic Thermometer is substantial equivalence to Acute Ideas' Digital Thermometer Classic type and Flexible type.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

In terms of physical requirements and operating parameters, the Clinical Electronic Thermometer conforms to ASTM E1112, "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature", as well as IEC 60601-1 and IEC 60601-1-2 requirements.

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were not conducted using the Clinical Electronic Thermometer and predicate devices.

9. Conclusions:

The Clinical Electronic Thermometer has the same intended use and similar technological characteristics as predicate devices. Moreover, any differences in their technological characteristics that do exist would not have a significant effect on the safety or effectiveness of the device. Thus, the Clinical Electronic Thermometer is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 27 2004

Mr. Shine Wan  
Operation Manager  
Cotronic Manufacturing  
4F, Block 4, Fu Yuan Ind. Zone,  
Jiu Wei, Xi Xiang,  
Bao An Zone,  
Shen Zhen,  
CHINA

Re: K032434

Trade/Device Name: Clinical Electronic Thermometer  
Regulation Number: 21 CFR 880.2910  
Regulation Name: Clinical Electronic Thermometer  
Regulatory Class: II  
Product Code: FLL  
Dated: October 5, 2004  
Received: October 5, 2004

Dear Mr Wan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number(if known): K032434

Device Name: Clinical Electronic Thermometer

### Indications For Use:

The device measures the human body temperature from oral, armpit, and rectal.

The device is reuseable and intended for clinical or home use on people of all ages.

Prescription Use \_\_\_\_\_

AND/OR

Over-The-Counter Use ☒

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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### Concurrence of CDRH, Office of Device Evaluation (ODE)

*Paul Hubbard for Anthony Nelson*

(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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